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Total Number of Pages in This Submission: 50

Application Number	10/069242
Filing Date	June 18, 2002
First Named Inventor	Gilchrist
Art Unit	1651
Examiner Name	D.M. Naff
Attorney Docket Number	1821K

ENCLOSURES *(Check all that apply)*

- [X] Fee Transmittal Form
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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Tyco Healthcare Group LP		
Signature	Douglas Denninger		
Printed name	Douglas E. Denninger		
Date	September 29, 2005	Reg. No.	31752

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Gilchrist et al.

Docket No.: 1821K

Serial No. 10/069242

Art Unit: 1651

Filed: June 18, 2002

Examiner: D. M. Naff

For: CELL GROWTH SUBSTRATE

Mail Stop APPEAL
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TRANSMITTAL OF APPEAL BRIEF (PATENT APPLICATION 37 C.F.R.1.192)

Sir:

Transmitted herewith, in triplicate is the APPEAL BRIEF in this application, with respect to the Notice of Appeal mailed August 3, 2005.

FEE FOR FILING APPEAL BRIEF

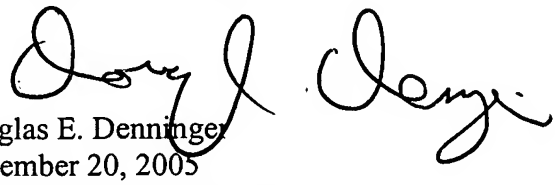
Pursuant to 37 C.F.R.1.17 (c), the fee for filing the Appeal Brief is $500.00 for a large entity.

Please charge Deposit Account No. 19-0254 in the name of the Kendall Co. in the amount of $500.00 to cover the filing fee.

The Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. 1.16 and 1.17, which may be required by this paper, or credit any overpayment to Deposit Account No. 19-0254.

A duplicate of this transmittal is enclosed.

Respectfully submitted,



Douglas E. Denninger
September 20, 2005
Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048
Registration No. 31,752
Phone: 508-261-8451
Fax: 508-261-6225

10-03-05

AF
JGW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND
INTERFERENCES

In re Application of:

Gilchrist et al.

Docket No.: 1821K

Serial No. 10/069242

Art Unit: 1651

Filed: June 18, 2002

Examiner: D. M. Naff

For: CELL GROWTH SUBSTRATE

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APPELLANTS' BRIEF

37 C.F.R. 1.192

This brief is in furtherance of the Notice of Appeal filed August 3, 2005. The Appeal Brief is transmitted herewith, in triplicate.

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Accompanying papers filed with Appellants' Brief are:

(1) TRANSMITTAL OF APPEAL BRIEF FEE in duplicate, authorizing payment of the requisite fee under 37 C.F.R.1.17 (c), including any fees necessary for an extension of time.

The filing of this Appeal Brief is timely as shown below:

(1) A Final Office Action was mailed May 3, 2005, rejecting Claims 1, 2, 4-7, 9, 10, 12-16, 18 and 19, pending in the application.

(2) A Notice of Appeal was timely mailed pursuant to 37C.F.R.1.8 on August 3, 2005.

This Appeal is from the Final Office Action rejecting claims 1, 2, 4-7, 9, 10, 12-16, 18, and 19.

The brief contains, in order, the following items under their respective headings:

I. REAL PARTY IN INTEREST
II. RELATED APPEALS AND INTERFERENCES
III. STATUS OF CLAIMS
IV. STATUS OF AMENDMENTS
V. SUMMARY OF CLAIMED SUBJECT MATTER
VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL
VII. ARGUMENT
VIII. CLAIMS APPENDIX

I. REAL PARTY IN INTEREST

The real party in interest is Tyco Healthcare Group LP, having a principal place of business at 15 Hampshire Street, Mansfield, Massachusetts, 02048.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellants, the appellants' legal representative, or assignee, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1, 2, 4-7, 9, 10, 12-16, 18, and 19 are pending.

Claims 1, 2, 4-7, 9, 10, 12-16, 18, and 19 are being appealed.

Pending Claims 1 and 2 have been amended.

Claim 3 has been cancelled.

Pending Claims 4-7 have been amended.

Claim 8 has been cancelled.

Pending Claims 9 and 10 have been amended.

Claim 11 has been cancelled.

Pending Claims 12, 13, and 14 have been amended.

Pending Claim 15 is pending as submitted.

Pending Claim 16 has been amended.

Claim 17 has been cancelled.

Pending Claims 18 and 19 have been amended.

IV. STATUS OF AMENDMENTS

No amendments to the claims have been made subsequent to the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention provides a cell culture growth substrate, adapted to sustain growth of living cells, that comprises a water soluble glass matrix comprising at least a portion of its surface coated with living cells, wherein the water soluble glass of the water soluble glass matrix comprises at least one metallic ion or boron

containing compound capable of conferring antimicrobial protection or enhanced cell growth, or both.

Reference is made to page 3, lines 11-16 and page 7, lines 9-30 of the specification. The present invention also provides a method for using the cell culture growth substrate in the growth of living tissue. Reference is made to page 40, lines 28-32, of the specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(a) The Examiner alleges that Claims 18 and 19 are indefinite, under the second paragraph of 35 U.S.C.112, as being indefinite for failing to particularly point out and distinctly the invention.

(b) The Examiner alleges that Claims 1, 2, 4-7, 9, 10, 12, 18 and 19 are patentably distinguishable over the Burnie et al. publication entitled "Controlled Release Glasses (C.R.G.) For Biomedical Uses," in view of WO 98/54104 to Gilchrist et al, and if necessary further in view of U.S. Patent no. 4,748,121 to Beaver et al.

(c) The Examiner alleges that Claims 13-16 are patentably distinguishable over the Burnie et al. publication entitled "Controlled Release Glasses (C.R.G.) For Biomedical Uses," in view of WO 98/54104 to Gilchrist et al., and if necessary, further in view of U.S. Patent No. 4,748,121 to Beaver et al., and further in view of U.S. Patent No. 5,811,302 to Duchayne et al.

VII. ARGUMENT

REJECTIONS UNDER 35 U.S.C.112, SECOND PARAGRAPH

Claims 18 and 19 are not indefinite for failing to particularly point out and distinctly claim the invention.

The Examiner has rejected Claims 18 and 19 under 35 U.S.C.112, second paragraph, as being indefinite in failing to particularly point out and distinctly claim the invention.

The Examiner states that more is required to be set forth to describe the claimed process, than the single step of providing a substrate. While the Examiner may believe that Claim 18 is confusing and unclear, the originally submitted specification clearly supports Claim 18, and the method as described in Claim 18.

Claim 18 is a method for encouraging growth of living tissue by providing the substrate of Claim 1. The substrate of Claim 1 is a cell culture growth substrate, adapted to sustain growth of living cells, that comprises a water soluble glass matrix that comprises at least a portion of the surface coated with living cells, and wherein the water soluble glass of the water soluble glass matrix comprises at least one metallic ion or boron containing compound capable of conferring antimicrobial protection or enhanced cell growth, or both.

As disclosed at page 3, lines 7-9, Appellants state that the water soluble glass acts as a support or matrix for cell growth and hence the glass has utility in tissue engineering. As shown further, at page 4, lines 1-6, of the present application, the water soluble glass acts as a cell support matrix and will function as such in vivo (defined as in a living body). The result of this, as stated by Appellants, is that the graft containing the water soluble glass can be used directly in vivo (emphasis added) to provide a temporary biodegradable scaffold which will encourage ingrowth of surrounding tissues (emphasis added). Accordingly, the specification supports Claim 18 that is a method for encouraging growth of living tissue by providing the cell culture growth substrate as defined in Claim 1.

In light of the above, Appellants contend that Claim 18 is not indefinite, under 35 U.S.C.112. Claim 18 is not confusing and unclear. Claim 18 sets forth the process as supported by the specification.

Claim 19 is said to be confusing and unclear in not having antecedent basis for the term "an aqueous medium" appearing in line 2. Appellants contend that Claim 19 is neither confusing nor unclear.

As set forth Claim 19 is completely supported by the specification, at page 8, lines 1-24. The disclosure of page 8, lines 1-24, must be taken in context with the disclosure appearing on pages 3 and 4, and elsewhere in the specification. As such, the disclosure at page 8, lines 1-24 is an embodiment of the invention. There can be no doubt, however, that Claim 19 is fully supported by the disclosure at page 8, lines 1-24.

In light of the above, Appellants contend that Claim 19 is not indefinite, under 35 U.S.C.112. Claim 19 is neither confusing, nor unclear. Claim 19 sets forth the process, as supported by the specification

REJECTION OF CLAIMS 1, 2, 4-7, 9, 10, 12, 18, 19
UNDER 35 U.S.C. 103 (a)

Claims 1, 2, 4-7, 9, 10, 12, 18 and 19, are not unpatentable over the Burnie et al publication entitled, "Controlled Release Glasses (C.R.G.) For Biomedical Uses," in view of WO 98/54104 to Gilchrist et al., and if necessary, in further view of U.S. Patent No. 4, 748,121 to Beaver et al.

The Examiner has rejected Claims 1, 2, 4-7, 9, 10, 12, 18, and 19, as being unpatentable over Burnie et al, in view of Gilchrist et al, and if necessary, in further view of Beaver et al.

In this respect, the Examiner has stated that the Burnie et al. article discloses, in the paragraph bridging pages 244 and 245, the use of water-soluble glass substrate in monolayer cell culture. However, the water-soluble glass substrate is not comprised of the same material as that of Appellants' claimed invention. As recognized by the Examiner, the water-soluble glass substrate of Burnie et al. does not contain a boron-containing compound. The claimed invention of Applicants specified further that the water-soluble glass substrate must contain, alternatively to the boron-containing compound, a metallic ion.

Since the Examiner has stated that the rejection may be based on previous reasons, as well, Appellants are restating a portion of the Response to the first Office Action. The Examiner has concluded that the water-soluble glass substrate of Burnie et al. contains sodium, and as such would be similar to Appellants' claimed invention. This was not the intended meaning of Appellents' invention,and to clarify the invention, Claim 1 was amended. The amendment to Claim 1 makes clear that the metallic ion contained in Appellents' water-soluble glass substrate is a metallic ion that confers either antimicrobial protection or enhanced cell growth, or both. This is disclosed at page 7, lines 9-16 of the present application. Examples of such metallic ions included within the claimed invention are said to be silver, copper, magnesium, zinc, iron, cobalt, molybdenum, chromium, manganese, cerium, selenium, individually or in combination. It should be noted that sodium is not mentioned as a suitable metallic ion. The use of sodium in the water-soluble glass substrate is in connection with a completely different purpose. As explained on page 6, line 25

– page 7, line 2, of the present application, sodium containing oxides are used as glass modifiers that are non-toxic, and that influence the rate at which the water-soluble glass dissolves in fluids. The present Claim 1, clarifies the meaning of the metallic ions in the water-soluble glass, and thus does not include sodium as an ion within the metallic ions of Claim 1.

The WO/ 98/54104 document to Gilchrist et al. has been described as showing that water-soluble glass fibers may contain boron and/or silver ions. There is not however, any disclosure or suggestion that the materials of WO 98/54104 would be suitable for use as cell culture growth substrates.

Appellants' claimed invention is not related to the water-soluble glass compositions, but rather to cell culture growth substrates comprising the specific water soluble glass comprising a metallic ion or a boron-containing compound. As is evident from Gilchrist et al, the invention described therein does not relate to the water soluble glass, but rather to a method for producing fibers from the water soluble glass. In the absence of any direction in the Gilchrist et al patent to utilize the water soluble glass compositions in the production of cell culture growth substrates, there would be no motivation for one of ordinary skill in the art to substitute the water soluble glass of Gilchrist et al, for the water soluble glass used successfully by Burnie et al.

A teaching by Gilchrist et al that a particular water soluble glass can be formed into fibers, does not provide any inducement for one of skill in the art of producing cell culture growth substrates to utilize such material. Indeed, even more so, where another form of the water soluble glass was used successfully, as was done by Burnie et al.

To this point, therefore, Appellants contend there is no showing that would support a conclusion that one of ordinary skill would have been inclined to modify the Burnie et al teaching, by substituting the water soluble glass composition of the Gilchrist et al reference.

The Beaver et al. U.S. Patent No. 4,748,121 was said to disclose immobilizing biochemically active material, such as cells, on porous glass fibers. However, as described by the Examiner, the porous glass fibers are prepared from a composition containing silica, boric oxide, alkali metal oxide, and aluminum oxide. Appellants agree with the Examiner's representation of Beaver et al., and note that the glass of Beaver et al. differs significantly from the water soluble glass of Appellants' invention.

Appellants do not believe the teachings of Beaver et al. are in any way related to the Appellants' claimed invention. Beaver et al. do not describe the water soluble glass used by Appellants, or the production of cell culture growth substrates. Therefore, there is nothing in Beaver et al that would provide a reasonable basis for one of ordinary skill to be motivated to modify the Burnie et al reference so as to obtain the Appellants' claimed invention.

The Examiner has stated that the method Claims 18 and 19 are suggested by Burnie et al. and Gilchrist et al. Appellants contend that method Claims 18 and 19 are not suggested by Burnie et al and Gilchrist et al.

Claims 18 and 19 are method claims directed to encouraging growth of living tissue as a result of utilizing a particular cell culture growth substrate, as described in Claim 1.

As is apparent, Burnie et al relates to using controlled release glasses in monolayer cell culture. However, as admitted by the Examiner, the controlled release glass of Burnie et al. differs from the water soluble glass of Appellants' claims, that is used in the production of cell culture growth substrates that are used in the method of Claims 18 and 19 to encourage growth of living tissue.

The Gilchrist et al. reference discloses nothing relating to a method for encouraging growth of living tissue. The Gilchrist et al. reference describes a method for producing fibers.

Therefore, Appellants contend that the methods of Claims 18 and 19 are not suggested in any way by Burnie et al. and Gilchrist et al.

From the teachings of the Burnie et al publication, WO 98/54104 to Gilchrist et al, and U.S. Patent No. 4,748,121 to Beaver et al, Appellants contend there is neither any disclosure nor suggestion, of the water-soluble glass cell culture growth substrate of Appellants' invention. Furthermore, there is nothing to suggest that one of ordinary skill in the art would have been motivated to combine any or all of the cited references, to achieve Appellants' claimed invention.

With respect to the present invention, Appellants note that results obtained were unexpected and surprising as follows. The metallic ions of Appellants' claimed invention, as generally exemplified on page 7, lines 9-17, of the present application, are generally considered to be toxic to the human body. However, addition of the metallic ions to the water-soluble glass substrate of the present invention stimulated, rather than disrupted, cell growth. This is shown by the results of the examples at pages 35 to 40, of the present application as filed. This stimulatory effect was surprising and unexpected, and was contrary to the

commonly held views of those skilled in the art.

In light of the above, Appellants contend that Claims 1, 2, 4-7, 9, 10, 12, 18, and 19, are patentably distinguishable and not obvious, from the disclosure in Burnie et al, WO 98/54104 to Gilchrist et al, and U.S. Patent No. 4,748,121 to Beaver et al.

REJECTION OF CLAIMS 13 – 16
UNDER 35 U.S.C. 103 (a)

Claims 13-16 are not unpatentable over the Burnie et al publication, the WO 98/54104 patent to Gilchrist et al, and the U.S. Patent No. 4,748,121 to Beaver et al, and U.S. Patent No. 5,811,302 to Ducheyne et al.

The Examiner has rejected Claims 13-16, under 35 U.S.C. 103 (a) as being unpatentable over the Burnie et al. article, WO 98/54104, and U.S. Patent No. 4,748,121 as applied to claims 1, 2, 4-7, 9, 10, 12, 18, and 19, and further in view of U.S. Patent No. 5,811,302 to Ducheyne et al.

With respect to Ducheyne et al, the Examiner has noted column 4, lines 1-10, as disclosing the sintering of glass particles. Sintering is mentioned in Claims 13 and 15, and this is apparently the reason for the Examiner's inclusion of the Ducheyne et al reference.

It is evident that Claims 13-16 are dependent claims. Each of Claims 13-16 are dependent at least on Claim 1. Accordingly Claims 13-16 include all the limitations of Claim 1, which define the cell culture growth substrate. The cell culture growth substrate is defined as a water soluble glass matrix which

comprises at least a portion of its surface coated with living cells, wherein the water soluble glass of the water soluble glass matrix comprises at least one metallic ion or boron containing compound capable of conferring antimicrobial protection or enhanced cell growth, or both.

Claims 13-16 are directed to the water soluble glass matrix of the cell culture growth substrate of Claim 1. None of the Burnie et al., Gilchrist et al., or Beaver et al. references or any combination, discloses or suggests Appellants' claimed cell culture growth substrate that comprises the water soluble glass matrix.

Therefore, if one of skill in the art were to combine the teachings of Ducheyne et al, relating to sintering, with any of the other cited references, Appellants' claimed invention would not be obtained.

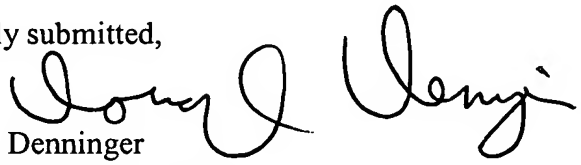
All of the comments herein regarding the Burnie et al. publication, the Gilchrist et al patent, and the Beaver et al. patent, as applied in the rejection of Claims 1, 2, 4-7, 9, 10, 12, 18 and 19, are hereby incorporated by reference, in respect of the rejection of Claims 13-16. The comments made herein establish that the Burnie et al publication, the Gilchrist et al patent and the Beaver et al patent, taken individually or in combination, do not disclose the cell culture growth substrate defined in Claim 1.

Claims 13-16 are dependent claims based upon independent Claim1, that is patentably distinct. Therefore, Claims 13-16 are also patentably distinguishable, and are not obvious, in view of the disclosures in the Burnie et al publication, WO 98/54104 to Gilchrist et al., U.S. Patent No. 4,748,121 to Beaver et al., and U.S. Patent No. 5,811,302 to Ducheyne et al.

CONCLUSION

For the reasons set forth above, reversal of the rejections of Claims 1, 2, 4-7, 9, 10, 12, 13-16, 18, and 19, is respectfully requested.

Respectfully submitted,



Douglas E. Denninger
Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048
Registration No. 31,752
Phone: 508-261-8451
Fax: 508-261-6225

Date:_____

VIII. CLAIMS APPENDIX

1. A cell culture growth substrate adapted to sustain growth of living cells, said substrate comprising a water-soluble glass matrix which comprises at least a portion of its surface coated with living cells, wherein the water-soluble glass of said water-soluble glass matrix comprises at least one metallic ion or boron-containing compound capable of conferring antimicrobial protection or enhanced cell growth, or both.

2. The substrate of Claim 1, wherein a portion of the surface of said substrate is coated with living cells.

4. The substrate of Claim 1, wherein the water-soluble glass is a phosphate glass.

5. The substrate of Claim 1, wherein said water-soluble glass comprises phosphorous pentoxide as glass former.

6. The substrate of Claim 1, wherein said water-soluble glass comprises an oxide or a carbonate of an alkali metal, an alkaline earth metal or a transition metal as glass modifier.

7. The substrate of Claim 6, wherein said glass modifier is sodium oxide, potassium oxide, magnesium oxide, zinc oxide or calcium oxide.

9. The substrate of Claim 1, wherein said water-soluble glass has a dissolution rate ranging from substantially zero to 2.0 mg/cm^2/hour at 38^0C.

10. The substrate of Claim 1, wherein said water-soluble glass enables a controlled release of additives in an aqueous medium.

12. The substrate of Claim 1, wherein said water-soluble glass matrix comprises water-soluble glass fibers.

13. The substrate of Claim 12, wherein said water-soluble glass fibers are sintered together to form a non-woven mat.

14. The substrate of Claim 1, wherein said water-soluble glass matrix comprises finely comminuted glass particles.

15. The substrate of Claim 14, wherein said finely comminuted glass particles are sintered together to form a porous structure.

16. The substrate of Claim 14, wherein said glass particles have an average diameter of from 15 microns to 6 mm.

18. A method to encourage growth of living tissue by providing the substrate of claim 1.

19. The method of Claim 18, wherein said method includes a step of delivering metal ions or boron to an aqueous medium at a rate which maintains a concentration of metal ions or boron in said aqueous medium of not less than 0.01 parts per million and not greater than 10 parts per million.